

**REMARKS**

Claims 1, 4, 7, and 10-13 have been amended to recite "A" at the beginning of the claim. These amendments have been made for clarification purposes only.

It is submitted that no new matter has been introduced by the foregoing amendments. Approval and entry of the amendments are respectfully solicited.

**Indefiniteness Rejection:**

Claims 1, 4, 7, and 10-13 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. (Paper No. 20070802 at 2).

In making the rejection, the Examiner asserted that "[e]very one of the above claims requires the article 'A' at the beginning of each claim." (*Id.*).

With a view towards furthering prosecution, and as suggested by the Examiner, claims 1, 4, 7, and 10-13 have been amended to recite "A" at the beginning of the claim. In view of the foregoing, the rejection of claims 1, 4, 7, and 10-13 is rendered moot. Accordingly, withdrawal of the rejection is respectfully requested.

**Rejections under 35 USC § 102:**

Claim 14 was rejected under 35 USC §102(b) as anticipated by Goehl, European Patent Application No. 0 111 663 ("Goehl"). (Paper No. 20070802 at 3).

For the reasons set forth below, the rejection, respectfully is traversed.

Goehl discloses a "[m]embrane in the form of a flat sheet, tube, or hollow fiber having a hydraulic permeability to water of 10-100 ml/m<sup>2</sup>/h/mmHg, and having a diffusive permeability to chloride (CL<sup>-</sup>) of more than 10 cm/sec x 10<sup>-4</sup>, preferably more than 12 cm/sec x 10<sup>-4</sup>, a diffusive permeability to vitamin B<sub>12</sub> of more than 2 cm/sec x

$10^4$ , and a diffusive permeability to inulin of more than  $0.5 \text{ cm/sec} \times 10^{-4}$ , and preferably more than  $1.0 \text{ cm/sec} \times 10^{-4}$ ." (Abstract).

In making the rejection over Goehl, the Examiner asserted only to "[s]ee the claims in the EP patent." (Paper No. 20070802 at 3).

As is well settled, ***anticipation requires "identity of invention."*** *Glaverbel Societe Anonyme v. Northlake Mktg. & Supply*, 33 USPQ2d 1496, 1498 (Fed. Cir. 1995). There must be **no difference between what is claimed and what is disclosed in the applied reference.** *In re Kalm*, 154 USPQ 10, 12 (CCPA 1967); *Scripps v. Genentech Inc.*, 18 USPQ2d 1001, 1010 (Fed. Cir. 1991). "Moreover, it is incumbent upon the Examiner to identify wherein each and every facet of the claimed invention is disclosed in the applied reference." *Ex parte Levy*, 17 USPQ2d 1461, 1462 (BPAI 1990). The Examiner is required to point to the disclosure in the reference "by page and line" upon which the claim allegedly reads. *Chiong v. Roland*, 17 USPQ2d 1541, 1543 (BPAI 1990).

Initially, we direct the Examiner's attention to the fact that inulin and its mixtures with thermoplastic polymers are rendered thermoplastically processable ***because the extrusion is conducted in the presence of water and/or plasticizer containing hydroxyl groups at temperatures of between 80 and 200°C.*** (See, e.g., Specification at page 4, line 24 to page 5, line 3 and claim 12.).

Indeed, it is surprising that inulin because of its so low molecular mass can be converted into a thermoplastically processable material. Thus, the possibility of obtaining the material as recited in the claim is subordinate to the solution of the problem of rendering inulin thermoplastically processable.

Here, claim 14 currently recites “[a] thermoplastically processable material comprising mixtures of inulin and/or oligofructans with thermoplastic polymers.” Goehl, on the other hand, **discloses** a membrane obtained from a polycarbonate solution in an organic solvent to which inulin is added as a **swelling agent**. (See Examples 1-3). In Goehl, the solution is extruded to obtain a sheet which **does not** contain inulin **in the thermoplastically processable form due to the absence of water and/or a polyol plasticizer during extrusion.** (*Id.*).

Accordingly, Goehl does not disclose each and every element of the claimed invention. For this reason, it is respectfully submitted that the rejection fails to present a *prima facie* case for anticipation and must be withdrawn.

Claim 14 was also rejected under 35 USC §102(b) as anticipated by Soon-Shiong *et al.*, WO 93/09176 (“Soon-Shiong”). (Paper No. 20070802 at 3).

For the reasons set forth below, the rejection, respectfully is traversed.

Soon-Shiong discloses “biocompatible materials (e.g., lipids, polycations, polysaccharides) which are capable of undergoing free radical polymerization, e.g., by using certain sources of light; methods of modifying certain synthetic and naturally occurring biocompatible materials to make polymerizable microcapsules containing biological material coated with said polymerizable materials, composites of said polymerizable materials, methods of making microcapsules and encapsulating biological cells (particularly islets of Langerhans) coated with polymerizable alginate or with a composite thereof (e.g., alginate and PEG).” (Abstract). Soon-Shiong “relates to

drug delivery systems relating to the foregoing, as well as bioadhesives and wound dressings made utilizing the foregoing technology." (*Id.*).

In making the rejection over Soon-Shiong, the Examiner asserted only to "[s]ee claims 1-5." (Paper No. 20070802 at 3).

As is well settled, ***anticipation requires "identity of invention"***. *Glaverbel Societe*, 33 USPQ2d at 1498. There must be **no difference between what is claimed and what is disclosed in the applied reference**. *Kalm*, 154 USPQ at 12; *Scripps*, 18 USPQ2d at 1010. "Moreover, it is incumbent upon the Examiner to identify wherein each and every facet of the claimed invention is disclosed in the applied reference." *Levy*, 17 USPQ2d at 1462. The Examiner is required to point to the disclosure in the reference "by page and line" upon which the claim allegedly reads. *Chiong*, 17 USPQ2d at 1543.

Again, we direct the Examiner's attention to the fact that inulin and its mixtures with thermoplastic polymers are rendered thermoplastically processable ***because the extrusion is conducted in the presence of water and/or plasticizer containing hydroxyl groups at temperatures of between 80 and 200°C.*** (See, e.g., Specification at page 4, line 24 to page 5, line 3 and claim 12.).

Indeed, it is surprising that inulin because of its so low molecular mass can be converted into a thermoplastically processable material. Thus, the possibility of obtaining the material as recited in the claim is subordinate to the solution of the problem of rendering inulin thermoplastically processable.

Here, claim 14 currently recites "[a] thermoplastically processable material comprising mixtures of inulin and/or oligofructans with thermoplastic polymers." Soon-

Shiong, on the other hand, **discloses** a modified biocompatible material of formula A-X, wherein A can be inulin and X is a **moiety** capable of free radical polymerization. (See claims 1-5). That, however, is **not** what is claimed. The material in Soon-Shiong is a compound having the formula A-X, which is **not** inulin. Moreover, it is also **not** “[a] thermoplastically processable material comprising mixtures of inulin and/or oligofructans with thermoplastic polymers” as currently claimed.

Accordingly, Soon-Shiong does not disclose each and every element of the claimed invention. For this reason, it is respectfully submitted that the rejection fails to present a *prima facie* case for anticipation and must be withdrawn.

Claim 14 was also rejected under 35 USC §102(b) as anticipated by Guttag, U.S. Patent No. 5,346,929 (“Guttag”). (Paper No. 20070802 at 3).

For the reasons set forth below, the rejection, respectfully is traversed.

Guttag discloses “biodegradable plastic made from a combination of at least one synthetic plastic polymer, at least one natural polymer and a natural polymer attacking agent and articles made therefrom.” (Abstract). Guttag further discloses that “[t]he biodegradable plastic … can be used for the formation of articles, including but not limited to, bottles, toys, gloves, boxes, dishes, bowls, syringes, cups and diapers.” (Col. 3, lines 40-44). Guttag also discloses that “[t]he term ‘natural polymer’ … refers to polymers found in nature which are easily broken down by natural decay bacteria” and “includes … particles of starch, inulin, cellulose and wood.” (Col. 2, lines 33-35).

In making the rejection over Guttag, the Examiner asserted only to “[s]ee claims 1 and 11 that recite inulin with polymers.” (Paper No. 20070802 at 3). The

Examiner asserted that “[s]ince inulin is the same, then it is inherently ‘thermoplastically processable.’” (*Id.*)

As is well settled, ***anticipation requires “identity of invention.”*** *Glaverbel Societe*, 33 USPQ2d at 1498. There must be **no difference between what is claimed and what is disclosed in the applied reference.** *Kalm*, 154 USPQ at 12; *Scripps*, 18 USPQ2d at 1010. “Moreover, it is incumbent upon the Examiner to identify wherein each and every facet of the claimed invention is disclosed in the applied reference.” *Levy*, 17 USPQ2d at 1462. The Examiner is required to point to the disclosure in the reference “by page and line” upon which the claim allegedly reads. *Chiong*, 17 USPQ2d at 1543.

Again, we direct the Examiner’s attention to the fact that inulin and its mixtures with thermoplastic polymers are rendered thermoplastically processable ***because the extrusion is conducted in the presence of water and/or plasticizer containing hydroxyl groups at temperatures of between 80 and 200°C.*** (See, e.g., Specification at page 4, line 24 to page 5, line 3 and claim 12.).

Indeed, it is surprising that inulin because of its so low molecular mass can be converted into a thermoplastically processable material. Thus, the possibility of obtaining the material as recited in the claim is subordinate to the solution of the problem of rendering inulin thermoplastically processable.

Here, claim 14 currently recites “[a] thermoplastically processable material comprising mixtures of inulin and/or oligofructans with thermoplastic polymers.” Guttag, on the other hand, ***discloses*** a biodegradable plastic material comprising a synthetic plastic polymer, a natural polymer, which can be inulin, and a microorganism or an

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enzyme as polymer attacking agent. (Col. 2, lines 36-51). The molded articles obtainable from the plastic material **cannot** contain inulin as recited in claim 14 due to the nature of the illustrative synthetic polymer used - the extrusion of which excludes the presence of water and/or polyol plasticizers. (Col. 4, lines 11-16).

Accordingly, Guttag does not disclose each and every element of the claimed invention. For this reason, it is respectfully submitted that the rejection fails to present a *prima facie* case for anticipation and must be withdrawn.

Claim 14 was also rejected under 35 USC §102(e) as anticipated by Van Haveren *et al.*, U.S. Patent No. 6,313,203 ("Van Haveren"). (Paper No. 20070802 at 4).

For the reasons set forth below, the rejection, respectfully is traversed.

Van Haveren discloses that "[n]atural cyclic polyalcohols such as polyfructoses and dehydration products of sugar alcohols can be used for stabilising thermoplastic polymers, at a ratio of 0.001-5 phr of polyol with respect to the polymer." (Abstract). "The cyclic polyol is in particular inulin or sorbitan. The polymer to be stabilised is in particular PVC, PE, PP or a halogenated rubber." (*Id.*)

In making the rejection over Van Haveren, the Examiner asserted only that "[t]he claims show a mixture of a thermoplastic polymer with inulin. See claim 4." (Paper No. 20070802 at 4).

Initially, we note that Van Haveren is **not** a proper reference to be applied against U.S. Application Serial No. 09/936,534. The international filing date for the present application is March 14, 2000. The international application also claims benefit to Italian application no. TO99A000199 filed March 15, 1999. The Van Haveren U.S.

patent cited by the Examiner, however, did not issue until November 6, 2001 more than two years after the Italian priority date of the present application and more than one year after the international filing date of the present application.<sup>1</sup>

In view of the foregoing, Van Haveren is not prior art to the present application. Therefore, it is respectfully submitted that the rejection is insufficient as a matter of law and must be withdrawn. See *Ex parte Jarvest*, 2001 WL 35811155, \*5 (BPAI 2001) (unpublished) ("Hannah is not prior art to the present application. Accordingly, the rejection of the claims as unpatentable over Hannah is reversed."); *Ex parte Brettschneider*, 2007 WL 1537610, \*2 (BPAI 2007) (unpublished) ("Brettschneider '930 was published July 4, 2002, ... and is therefore not available as prior art against the instant invention. Appellant is thus correct that Brettschneider '930 cannot be relied upon in rejecting Appellant's claims ....").

**Rejection under 35 USC § 103:**

Claims 1, 4, 7, and 10-13 were rejected under 35 USC § 103(a) as being unpatentable over Leo, U.S. Patent No. 5,419,283 ("Leo") and Wang, U.S. Patent No. 5,922,379 ("Wang") in view of Anantharaman *et al.*, U.S. Patent No. 5,952,033 ("Anantharaman") and further in view of Van Haveren *et al.*, U.S. Patent No. 6,313,203 ("Van Haveren") and Bengs *et al.*, U.S. Patent No. 6,406,530 ("Bengs"). (Paper No. 20070802 at 4).

For the reasons set forth below, the rejection, respectfully is traversed.

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<sup>1</sup> The §102(e) date for Van Haveren is August 4, 1999, almost six months after the Italian priority date of the present application. See MPEP § 706.02(a).

Leo discloses “[a] chew toy for animals [that] is molded into the shape of a familiar animal food item, such as a dog bone, from a polymer composition which is both edible and degradable. The composition is essentially comprised of a starch material and a degradable ethylene copolymer, preferably poly-ethylene-acrylic acid or poly-ethylene, vinylalcohol.” (Abstract.) Leo further discloses that “[p]lasticizers and edible lubricants can also be added to the composition.” (*Id.*).

Wang discloses “a biodegradable protein/starch-based thermoplastic composition.” (Abstract). “The composition is particularly useful in preparing low ratio expanded foams. Natural cellulosic fibers such as grass fiber, wood fiber, chopped straw, bagasse, etc. function as reinforcement filler. A metallic salt hydrate is added to improve mechanical properties of the protein/starch-based thermoplastic. The composition is processed by conventional methods, such as extrusion and injection molding, into packaging material or articles that are low density, high compressive strength, tensile strength, and good resilience.” (*Id.*).

Anantharaman discloses “[a] gelatinized cereal product which contains a plant material which is a source of inulin; for example chicory.” (Abstract). “Sufficient of the plant material is included to provide at least about 0.25% by weight of inulin on a dry basis. The cereal product may be used as a pet food or breakfast cereal.” (*Id.*).

Van Haveren discloses that “[n]atural cyclic polyalcohols such as polyfructoses and dehydration products of sugar alcohols can be used for stabilising thermoplastic polymers, at a ratio of 0.001-5 phr of polyol with respect to the polymer.” (Abstract). “The cyclic polyol is in particular inulin or sorbitan. The polymer to be stabilised is in particular PVC, PE, PP or a halogenated rubber.” (*Id.*).

Bengs discloses a “[t]hermoplastic mixture based on biopolymers for producing shaped biodegradable articles with improved properties ....” (Abstract). “A novel thermoplastic mixture based on biopolymers, in particular on starch, features the presence of lignin and is used for producing shaped biodegradable articles with improved properties, preferably with improved mechanical properties.” (*Id.*).

In making the rejection, the Examiner asserted that “[b]oth Leo and Wang teach biodegradable thermoplastic products.” (Paper No. 20070802 at 4).

The Examiner acknowledged, however, that “[b]oth patents **do not** teach inulin.” (*Id.* at 5) (emphasis added).

To fill the acknowledged gap, the Examiner relied on Van Haveren as disclosing “inulin” as “a polysaccharide, is known to be a stabilizer for extrudable thermoplastics.” (*Id.*). The Examiner further relied on Bengs for “teach[ing] a mixture of starches including inulin, used in biodegradable thermoplastic materials that can be thermoplastically processable using techniques such as injection holding or extrusion, “ and “[n]ote that the mixture of starches is given to be in an amount 33-90%.” (*Id.*).

The Examiner relied on Ananthararman for “teach[ing] [that] the use of inulin in pet food products is beneficial in an amount of at least 0.25%. See col 1, which states that inulin promotes bifido- and lacto-bacteria in the GI tract at the expense of pathogens and is very beneficial for animals and inulin has been used as a vet diet for pets. Col 1, 50-52. col 2, lines 7-12.” (*Id.*). The Examiner asserted that “[t]his patent establishes that inulin has been used for pet foods and that ‘for pet foods, their use has been confined to specialty veterinary products such as the Eukanuba

product and to pet treats. Similarly, for human foods, their use has been confined to specialty products.' (Col. 2, lines 7-10)." (*Id.*).

The Examiner then contended that "while Leo and Wang establish biodegradable, thermoplastically processable starch containing products have been used for pet chews, Anantharaman et al., by establishing that inulin provides benefits for the GI tract for pets, and that inulin has been used for pet treats, motivates one of ordinary skill in the art to incorporate inulin in biodegradable, thermoplastically processable products of Leo and Wang in pet products with plasticizers or glycerol, etc." (*Id.* at 6). The Examiner further contended "the patents to Bengs et al. and Van Haveren et al. show shaped, extrudable, biodegradable, inulin containing articles wherein inulin additionally acts as a stabilizer for such a thermoplastically processable compositions (Van Havernan et al.)" and the "[p]atents to Anatharaman et al. and Van Haveren et al. show inulin amounts of 'at least 0.25%' and mixtures of starch including inulin between 33% to 90%, and to determine amounts for various pet chew articles would have been obvious based on such disclosure." (*Id.*). The Examiner then contended "[w]ith regard to claim 13, Leo shows a bone" and "[w]ith regard to claim 12, the Anantharaman et al. patent shows the extrusion temperature at col 4, line 10-15." (*Id.*).

Initially, we note that Bengs is *not* a proper reference to be applied against U.S. Application Serial No. 09/936,534. The international filing date for the present application is March 14, 2000. The international application also claims benefit to Italian application no. TO99A000199 filed March 15, 1999. The Bengs U.S. patent cited by the Examiner, however, did not issue until June 18, 2002 more than three

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years after the Italian priority date of the present application and more than two years after the international filing date of the present application.<sup>2</sup>

We also note that Van Haveren is *not* a proper reference to be applied against U.S. Application Serial No. 09/936,534. As stated above, the international filing date for the present application is March 14, 2000. The international application also claims benefit to Italian application no. TO99A000199 filed March 15, 1999. The Van Haveren U.S. patent cited by the Examiner, however, did not issue until November 6, 2001 more than two years after the Italian priority date of the present application and more than one year after the international filing date of the present application.<sup>3</sup>

In view of the foregoing, the U.S. patent to Bengs and the U.S. patent to Van Haveren cited by the Examiner are *not* prior art to the present application. Accordingly, the rejection is deficient as a matter of fact and law and must be withdrawn for this reason alone. See *Ex parte Jarvest*, 2001 WL 35811155, \*5 (BPAI 2001) (unpublished) (“Hannah is not prior art to the present application. Accordingly, the rejection of the claims as unpatentable over Hannah is reversed.”); *Ex parte Brettschneider*, 2007 WL 1537610, \*2 (BPAI 2007) (unpublished) (“Brettschneider '930 was published July 4, 2002, ... and is therefore not available as prior art against the instant invention. Appellant is thus correct that Brettschneider '930 cannot be relied upon in rejecting Appellant's claims under 35 U.S.C. § 103(a).”).

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<sup>2</sup> The §102(e) date for Bengs is March 13, 2000, almost one year after the Italian priority date of the present application. See MPEP § 706.02(a).

<sup>3</sup> The §102(e) date for Van Haveren is August 4, 1999, almost six months after the Italian priority date of the present application. See MPEP § 706.02(a).

Thus, **two** out of the Examiner's **five** references relied on to make this obviousness rejection are not prior art. Assuming *arguendo* that the Examiner can make out a *prima facia* case for obviousness with the remaining **three** references (*i.e.*, Leo, Wang, and Anantharaman), **which she can not**, we demonstrate below that such a rejection would be deficient and fails to disclose or suggest the claimed invention.

It is well settled that the Examiner bears the burden to set forth a *prima facie* case of unpatentability. *In re Glaug*, 62 USPQ2d 1151, 1152 (Fed. Cir. 2002); *In re Oetiker*, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992); and *In re Piasecki*, 223 USPQ 785, 788 (Fed. Cir. 1984). If the PTO fails to meet its burden, then the applicant is entitled to a patent. *In re Glaug*, 62 USPQ2d at 1152.

When patentability turns on the question of obviousness, as here, the search for and analysis of the prior art by the PTO should include evidence relevant to the finding of whether there is a teaching, motivation, or suggestion to select and combine the documents relied on by the Examiner as evidence of obviousness. *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1731-32 (2007) (the obviousness "**analysis should be made explicit**" and the teaching-suggestion-motivation test is "**a helpful insight**" for determining obviousness) (emphasis added); *McGinley v. Franklin Sports*, 60 USPQ2d 1001, 1008 (Fed. Cir. 2001). Moreover, the factual inquiry whether to combine documents must be thorough and searching. And, as is well settled, the teaching, motivation, or suggestion to combine "**must be based on objective evidence of record.**" *In re Lee*, 61 USPQ2d 1430, 1433 (Fed. Cir. 2002) (emphasis added). See also *Examination Guidelines for Determining Obviousness*, 72 Fed. Reg. 57526, 57528 (October 10, 2007) ("The key to supporting any rejection under 35

U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious.”).

Here, the rejection is devoid of *any* evidence - or even argument - in support of the proposed combination. All that is there are conclusory remarks and a conclusory statement that “Leo and Wang establish biodegradable, thermoplastically processable starch containing products [that] have been used for pet chews, [and] Anantharaman et al., by establishing that inulin provides benefits for the GI tract for pets, and that inulin has been used for pet treats, motivates one of ordinary skill in the art to incorporate inulin in biodegradable, thermoplastically processable products of Leo and Wang in pet products with plasticizers or glycerol, etc.” (Paper No. 20070802 at 6). What the rejection should have done, but did not, was to explain on the record *why* one skilled in this art would modify the disclosure of Leo and Wang in view of Anantharaman to arrive at the claimed invention. As is well settled, an Examiner cannot establish obviousness by locating references which describe various aspects of a patent applicant's invention without also providing evidence of the motivating force which would impel one skilled in the art to do what the patent applicant has done. *Takeda Chem. Indus., Ltd v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1357 (Fed. Cir. June 28, 2007) (indicating that “it remains necessary to identify *some reason* that would have led a chemist to modify a known compound in a particular manner to establish *prima facie* obviousness of a new claimed compound”) (emphasis added); *Ex parte Levengood*, 28 USPQ2d 1300, 1301-02 (BPAI 1993). But this is precisely what the Examiner has done here. Thus, the rejection is legally deficient and should be withdrawn for this reason alone.

Notwithstanding the legally insufficient nature of the rejection, we note that the rejection is also factually insufficient to support a rejection under § 103(a). In doing so we observe that obviousness cannot be based upon speculation, nor can obviousness be based upon possibilities or probabilities. Obviousness **must** be based upon facts, “cold hard facts.” *In re Freed*, 165 USPQ 570, 571-72 (CCPA 1970). When a conclusion of obviousness is not based upon facts, it cannot stand. *Ex parte Saceman*, 27 USPQ2d 1472, 1474 (BPAI 1993). Further, “to establish *prima facie* obviousness of a claimed invention, **all claim limitations must be taught or suggested by the prior art.**” MPEP § 2143.03 (citing *In re Royka*, 180 USPQ 580 (CCPA 1974)) (emphasis added).

Assuming *arguendo* that Leo and Wang is properly combinable with Anantharaman, which it is not, such a combination does not disclose or suggest the claimed invention. The obviousness rejection of claims 1, 4, 7, and 10-13 is based on the **erroneous** assumption that one of ordinary skill in the art would have been motivated to incorporate inulin in the thermoplastically processable **starch-based** products of Leo and the **starch-protein/thermoplastic compositions** of Wang.

However, we note that inulin is a polysaccharide, which for structure and molecular mass is completely different from starch. Starch is formed from two components. The first component is linear glucan with glucose units 1,4 - linked. The second component is amylopectin, which is a branched glucan. In contrast, inulin is an oligofructan, wherein the fructofuranose units are 2,1 - linked and its degree of polymerization is between 2 to 60, whereas the degree of polymerization for starch is orders of magnitude greater. Indeed, it is surprising that inulin because of its so low

molecular mass can be converted into a thermoplastically processable material. Thus, the possibility of obtaining the chewable articles as recited in the claim is subordinate to the solution of the problem of rendering inulin thermoplastically processable. The Examiner has yet to come to grips with these glaring factual differences.

Thus, the Examiner's reasoning is factually and legally flawed. To arrive at the currently claimed chewable article it is necessary to know the conditions which render inulin thermoplastically processable, which is not disclosed by any of the cited documents. In this regard, again, we direct the Examiner's attention to the fact that inulin and its mixtures with thermoplastic polymers are rendered thermoplastically processable ***because the extrusion is conducted in the presence of water and/or plasticizer containing hydroxyl groups at temperatures of between 80 and 200°C.*** (See, e.g., Specification at page 4, line 24 to page 5, line 3 and claim 12.). See *In re Kumar*, 418 F.3d 1361, 1368 (Fed. Cir. 2005) ("Although published subject matter is 'prior art' for all that it discloses, in order to render an invention unpatentable for obviousness, the prior art **must** enable a person of ordinary skill to make and use the invention.") (emphasis added). In addition, missing from the cited documents, and the Examiner's analysis, is a reasonable expectation of success of obtaining articles having the necessary resistance to chewing and other correlated mechanical properties (including, among others, the proper taste and aroma rendering the toy acceptable to pets), which is required to motivate one of skill in the art to use inulin in place of the starch disclosed in Leo.

A *prima facie* case of obviousness requires that the rejection describe with specificity **why** one skilled in the art would have combined the references to arrive at

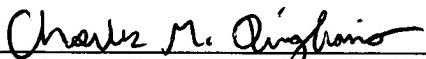
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the claimed invention. *In re Dembiczak*, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999) ("Our case law makes clear that ***the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references.***") (emphasis added). Here, the substitution of inulin for starch to motivate the Examiner's combination of the cited references in an attempt to arrive at the claimed chewable article is based on an improper hindsight reconstruction of the claimed invention.

In view of the foregoing, it is respectfully submitted that the rejection has been rendered moot. Accordingly, withdrawal of the rejection is respectfully requested.

Accordingly, for the reasons set forth above, entry of the amendments, withdrawal of the rejection, and allowance of the claims are respectfully requested. If the Examiner has any questions regarding this paper, please contact the undersigned.

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on February 8, 2008.



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